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Clinical evaluation of VGEL supraglottic airway device (SGAD) in comparison to a classical laryngeal mask and endotracheal intubation in cats during spontaneous and controlled mechanical ventilation

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Clinical evaluation of VGEL supraglottic airway device (SGAD) in comparison to a classical laryngeal mask and endotracheal intubation in cats during spontaneous and controlled mechanical ventilation

The objective of this clinical trial was to compare airway management during anaesthesia with spontaneous and controlled mechanical ventilation (CMV) using a cat-specific supraglottic airway device (VGEL), a classical laryngeal mask (LM) or an endotracheal tube (ETT).

After premedication 45 healthy cats were randomly allocated to one of 3 groups to secure the airway: 1) VGEL, 2) LM or 3) ETT (cuff pressure = 20 cm H_2O) and anaesthetized for elective procedures. The dose of propofol necessary to insert the VGEL, LM or ETT, the number of attempts for insertion and the leakage during spontaneous ventilation and CMV at different peak inspiratory pressures (8/10/12/14 and 16 cm H_2O) were recorded. A leakage greater than 20% of the tidal volume was defined as an exclusion criteria.

Cats with VGEL required 3 mg kg^{-1} [2- 5] of propofol for successful placement which was significantly less compared to 5 mg kg^{-1} [3- 7] for ETT ($p = 0.005$). No significant difference was observed between the VGEL and LM (3 mg kg^{-1} [2- 7]) or between ETT and LM regarding the total dose of propofol.

Significantly more cats had to be excluded in the ETT group due to leakage > 20% during CMV at all pressure settings.

In conclusion VGEL is a practicable alternative to the LM and ETT for airway management during anaesthesia and for CMV up to 16 cm H_2O in healthy cats. Insertion of VGEL can be achieved at a more superficial level of anaesthesia and showed siginificantly less leakage during CMV compared to ETT.

cat, controlled mechanical ventilation, endotracheal tube, laryngeal mask, VGEL

Atemwegsmanagement für anästhesierte Katzen mittels einer katzenspezifischen (VGEL) sowie einer klassischen Larynxmaske (LM) und eines endotrachealen Tubus (ETT) wurde während spontaner sowie kontrolliert mechanischer Ventilation verglichen.

Nach Prämedikation wurden 45 Katzen zufällig in 3 verschiedene Gruppen eingeteilt: 1) VGEL, 2) LM oder 3) ETT (Cuff = 20 cm H_2O) und für elektive Eingriffe anästhesiert. Die benötigte Dosis Propofol für die Insertion von VGEL, LM und ETT, die Anzahl Insertionsversuche sowie das Leck während spontaner und kontrolliert mechanischer Ventilation bei verschiedenen Drücken (8/10/12/14 und 16 cm H_2O) wurden aufgezeichnet. Als Ausschlusskriterium wurde ein Leck grösser als 20% des Atemzugvolumens definiert.

Katzen mit VGEL benötigten 3 mg kg^{-1} [2- 5] Propofol für deren Einsetzen; dies war siginfikant weniger im Vergleich zu 5 mg kg^{-1} [3- 7] für ETT (p = 0.005). Es wurde kein signifikanter Unterschied zwischen VGEL und LM (3 mg kg^{-1} [2- 7]) oder zwischen ETT und LM diesbezüglich beobachtet.

Signifikant mehr Katzen mussten in der ETT Gruppe wegen eines Lecks > 20% bei allen Druckeinstellungen ausgeschlossen werden.

VGEL ist eine gute Alternative zu LM und ETT für die Sicherung der Atemwege während der Anästhesie sowie für die mechanische Ventilation mit Drücken bis zu 16 cm H_2O ist. VGEL kann im Vergleich zum ETT bei oberflächlicherer Anästhesie eingesetzt werden und zeigt signifikant weniger Leck während kontrolliert mechanischer Ventilation.

Katze, kontrolliert mechanische Ventilation, endotrachealer Tubus, Larynxmaske, VGEL

Clinical evaluation of VGEL supraglottic airway device (SGAD) in comparison to a classical laryngeal mask and endotracheal intubation in cats during spontaneous and controlled mechanical ventilation

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Abstract

Objective To compare airway management during induction of anaesthesia, spontaneous and controlled mechanical ventilation (CMV) using a cat-specific supraglottic airway device (VGEL), a classical laryngeal mask (LM) or an endotracheal tube (ETT).

Study design Prospective, randomized clinical trial.

Animals Forty-five healthy cats.

Methods After premedication cats were randomly allocated to one of three groups to secure the airway: 1) VGEL, 2) LM or 3) ETT (cuff pressure = 20 cm H_2O) and anaesthetized for elective procedures. The dose of propofol necessary to insert the VGEL, LM or ETT, the number of attempts for insertion and the leakage during spontaneous ventilation and CMV at different peak inspiratory pressures (8/10/12/14 and 16 cm H_2O) were recorded. A leakage greater than 20% of the tidal volume was defined as an exclusion criteria.

Values are given as median [range]. Significance was set at $p < 0.05$.

Results Cats with VGEL required 3 mg kg^{-1} [2- 5] of propofol for successful placement which was significantly less compared to 5 mg kg^{-1} [3- 7] for endotracheal intubation (p = 0.005). No significant difference was observed between the VGEL and LM (3 mg kg^{-1} [2- 7]) or between ETT and LM regarding the total dose of propofol.

Significantly more cats had to be excluded in the ETT group due to leakage > 20% during CMV at all pressure settings.

Conclusions and clinical relevance VGEL is a practicable alternative to the LM and ETT for securing the airway after induction of anaesthesia and for CMV up to 16 cm H_20 in healthy cats. Insertion of VGEL can be achieved at a more superficial level of anaesthesia compared with endotracheal intubation and showed siginificantly less leakage during CMV compared to ETT.

Keywords cat, controlled mechanical ventilation, endotracheal tube, laryngeal mask, VGEL

Introduction

Securing of the upper airway is a major concern during general anaesthesia to ensure patency of the airway and the possibility to apply controlled mechanical ventilation (CMV). The endotracheal tube (ETT) is still considered to be the ‚gold standard' in veterinary practice, but may be associated with several life threatening complications in cats such as soft tissue swelling, arytenoidal tears or even tracheal rupture (Hardie et al. 1999; Lawrence et al. 1999; Mitchell et al. 2000; Hofmeister et al. 2007). Endotracheal intubation is associated with a two-fold increase in odds of death in cats (Brodbelt et al. 2007). Aforementioned complications can be minimized by using a SGAD such as a classical laryngeal mask (LM) or a VGEL supraglottic airway device. Even though the LM was developed for human medicine it has been successfully used in cats (Asai et al. 1998; Cassu et al. 2004); nevertheless it does not mirror the oropharyngeal anatomy of cats. The VGEL is a cat-specific SGAD consisting of a non-inflatable cuff that forms a seal around the laryngeal inlet and an inflatable device to increase the seal pressure (Crotaz 2010). In a clinical study the time from first injection of propofol to the first clinically acceptable reading on the capnograph was significantly shorter with the VGEL compared to ETT (van Oostrom et al. 2013). As well, cats receiving an ETT showed significantly more stridor during recovery, even though this could not be definitively attributed to its use alone.

The aim of our prospective, randomized clinical study was to compare depth of anaesthesia required and total attempts for placement of VGEL, LM and the ETT and the occurrence of leakage during spontaneous and CMV in anaesthetized cats. Our hypothesis was that the placement of the VGEL would require less propofol and fewer attempts than the groups LM and ETT. Furthermore, we hypothesised that the leakage in group VGEL would occur at lower and higher pressure settings than with ETT and LM, respectively.

Material and Methods

This prospective randomised clinical study had ethical approval from the Swiss Federal Ethics Committee of Canton Zurich (198/ 2012). Randomisation was accomplished by using an opaque envelope.

Animals & anaesthesia

Forty-five client-owned cats (37 European Shorthair, 4 Main Coon, 2 Birman, 1 British Shorthair, 1 Burmese), 15 males and 30 females, weighing 3.4 ± 0.8 kg were included.
The cats were found to be healthy upon clinical examination and classified as ASA I or II. Exclusion criteria were a body weight below 2 kg, a history of respiratory or upper gastrointestinal problems, a body condition score of more than 7/9 and drugs other than nonsteroidal anti-inflammatory drugs. The cats underwent general anaesthesia for spaying (29 females), castration (14 males) or other elective surgery (1 lasering of an iris melanoma, 1 ureter stent).

Food, but not water, was withheld for at least 6 hours prior to anaesthesia.

Placement of airway device (part 1)

Anaesthesia was always performed by the same anaesthesist (SP). The anaesthesist remained unaware of the group allocation until an adequate level of anaesthesia for placement of an airway device was reached based on a predefined score (Appendix 1). After placing an intravenous catheter and starting an infusion of a cristalloid solution (Ringer-Laktat Fresenius; Kabi, Switzerland) at 5.0 mL kg^{-1} $hour^{-1}$ the cats were left undisturbed for at least 10 minutes in a cage. Thereafter the cats were premedicated with methadone 0.1 mg kg^{-1} (Methadon Streuli; Streuli Pharma AG, Switzerland) and diluted medetomidine 5 µg kg^{-1} (Dorbene; Graeub AG, Switzerland) mixed in a syringe filled up to 3 mL with sterile saline, given IV slowly over 3 minutes. After another 5 minutes, sedation was assessed using a sedation score (Navarrete et al. 2011) by the 'blinded' anaesthesist (SP). The cats were then preoxygenated for another 3 minutes and the following five predefined criteria (Gurney et al. 2009) for

adequate level of anaesthesia were assessed with the cat in sternal recumbency: palpebral reflex, jaw tone, protraction of tongue, reaction to the touch of the tongue (not epiglottis) with a laryngoscope and the reaction to spraying of the larynx with diluted lidocaine 2% (Kantonsapotheke Zürich, Switzerland). If any of these five criteria were not fulfilled a 1 mg kg^{-1} bolus of propofol (Propofol 1% MCT Fresenius, Kabi, Switzerland) was given over 20 seconds and the criteria reassessed after 20 seconds. Lidocaine spraying was repeated if necessary but a predefined maximum of 2 mg kg^{-1} was set. Only as soon as all five criteria were fullfilled was the anaesthesist made aware of the pre-determined treatment group and attempted the first insertion of the allocated airway device (VGEL: n = 15; LM: n = 15; ETT: n = 15). If this attempt failed because of coughing, retching or gagging another bolus of propofol of 1 mg kg^{-1} was given over 20 seconds and the next attempt was undertaken after 20 seconds. The administration of propofol boli was repeated until successful placement of the device was possible in sternal recumbency. The total amount of propofol needed and the number of attempts to place the airway device were recorded.

The VGEL was inserted while the tongue was pulled slightly outward with the opening of the cuff facing ventrally until the device could not be inserted further. VGEL sizes C1 to C6 (Docsinnovent Ltd, UK) were used according to the manufacturer's guidelines (http://docsinnovent.com/downloads/v-gel_Tech_Sheet-med.pdf). The LM (deflated) was inserted as described above with the VGEL. The LM was then inflated (volume according to guideline indicated on the cuff-balloon) to the point where it moved slightly rostrally to ensure correct placement according to the guidelines existing for dogs (Wiederstein & Moens 2008). LM size 1 (Soft Seal Laryngeal Mask, Portex) was used in all cats. The ETT (Mallinckrodt, Covidien, Mansfield, USA) was inserted with the aid of a laryngoscope and its cuff (low pressure- high volume) was inflated under control of a pressure gauge to a pressure of 20 cm H_2O. ETT sizes ranged from 3.5 to 4.5 mm of internal diameter and were selected

according to the hospital's guidelines. All airway devices were secured with a gauze around the neck.

The pediatric airway connector of a spirometer with capnography (NICO2, Respironics) was placed between the airway device and the Y-piece (internal diamter 12 mm) of the anaesthetic machine (Datex Ohmeda, Aespire). Anaesthesia was maintained with isoflurane vaporized in an oxygen/ air mixture (FiO_2 targeted at 50 %) at a flow of 2 L $minute^{-1}$ using a circle rebreathing system and adjusted at the anaesthesist's discretion.

If any cat without secured airway (not tracheally intubated) showed signs of upper airway obstruction or a pulse oxymetry reading of less than 90% for more than 60 seconds at any time during the study period an immediate endotracheal intubation was performed irrespective of the initial allocation and the cat excluded from further data collection (Figure 1).

Leakage during spontaneous and controlled mechanical ventilation (part 2)

When cats were at a stable level of anaesthesia 10 spontaneous breaths were recorded and thereafter CMV was initiated at a peak inspiratory pressure (PIP) of 8 cm H_2O and increased in increments of 2 cm H_2O up to a maximum of 16 cm H_2O.

A minimum of ten breaths was allowed for each pressure setting. To detect any leakage the difference between the inspiratory and exspiratory tidal volume (TV) in mL was continuosly monitored.

If a cat was breathing against the ventilator, level of anaesthesia was deepened and CMV re-attempted.

If a leakage greater than 20 % of TV occurred at a certain pressure setting the trial was stopped and all cats with a supraglottic airway device were endotracheally intubated. After collecting the data at 16 cm H_2O the study period was over (Figure 1) and cats followed standard surgical preparation and recovered with appropriate analgesia.

The exact leakage in ml breath^{-1} for each pressure setting was evalauted retrospectively by analysing the inspiratory and expiratory volume using a dedicated software (Analysis Plus; Novametrix Medical Systems, Conn., USA).

Statistics

A statistical power analysis (Erdfelder, Faul & Buchner, 1996) was performed for sample size estimation to determine the number of animals needed per group to detect a significant difference in propofol requirement and leakage, respectively. For part 1 this analysis was based on data from a published study done in dogs (Wiederstein et al. 2006) comparing the propofol requirement for placement of LM and ETT and for part 2 on the assumed pressure settings, at which all cats in the three groups would show a leakage of 20% of TV. With an alpha = 0.05 and a power of 0.8 the projected sample size resulted in 9 and 12 animals per group, respectively. We decided to include 15 animals per group to compensate for possible technical problems during data collection.

All data were analysed using Microsoft Office Excel 2011 (Microsoft Corp., WA, USA) and SPSS 21.0 (IBM Corp., NY). Continuous variables were analysed with the non-parametric Kruskal-Wallis test as data was not normally distributed. Discrete variables were analysed using the Fisher's test. Differences were considered statistically significant if $p < 0.05$. Data are reported as median [range].

Results

Forty-five cats were initially included in the study. Demographic data and sedation scores after premedication are shown in Table 1. No statistical significant differences were observed between groups with respect to age, weight, body condition score and sedation score. Drop out rate and time points are shown in Figure 1.

Placement of airway device (part 1)

Data of all 45 cats could be included in this part of the study. The VGEL group required significantly less propofol (3 [2- 5] mg kg^{-1}) compared to cats in group ETT (5 [3- 7] mg kg^{-1}). The median dose of propofol requirement in group LM was 3 [2- 7] mg kg-1. No significant difference in the total dose of propofol between the VGEL and LM and the ETT and LM group was found (Figure 2). In none of the cats was the maximum dose for lidocaine spray during airway device placement reached. Age, weight, body condition scores, total sedation scores and number of attempts did not have any influence on the total dose of propofol.There was no significant difference in the number of total insertional attempts between VGEL, LM and ETT.

Leakage during spontaneous and controlled mechanical ventilation (part 2)

Twelve of 15 cats in the VGEL group completed this part of the study: one cat showed signs of upper airway obstruction after insertion of the VGEL and evaluation was not possible during spontaneous ventilation, thus the VGEL removed and the cat excluded. Another cat had to be excluded at the pressure setting of 8 cm H_2O due to a low pulse oximetry reading (SpO_2 < 90%) and underwent immediate endotracheal intubation. A third cat had to be excluded at PIP level 16 cm H_2O due to technical problems with the ventilator (Figure 1). During spontaneous ventilation no cat showed a leakage greater than 20 % of TV.

There were significant differences regarding the occurrence of a leakage greater than 20% of the TV between the VGEL and the ETT (8 cm H_2O: $p = 0.035$, 10 cm H_2O: $p = 0.001$, 12 cm H_2O: $p = 0.001$, 14 cm H_2O: $p = 0.001$, 16 cm H_2O: $p = 0.001$) and the ETT and LM group (8

cm H_2O: $p = 0.007$, 10 cm H_2O: $p = 0.001$, 12 cm H_2O: $p = 0.001$, 14 cm H_2O: $p = 0.001$, 16 cm H_2O: $p = 0.001$) at all pressure settings (Figure 3). The ETT group had significantly more leakage at PIP pressures above 8 cm H_2O than groups VGEL and LM.

Discussion

One of the main findings of this study is that the total dose of propofol required for placement of a VGEL was statistically lower than for endotracheal intubation. The potentially lower dose of propofol can be advantageous by lowering the incidence of known side-effects such as hypoventilation, hypoxemia, apnea and hypotension (Keegan & Greene 1993; Branson & Gross 1994; Thurmon et al. 1994).

A study in cats showed no difference between VGEL and ETT regarding the amount of propofol required for insertion of the airway device (van Oostrom et al. 2013). They used potentially stronger sedation protocols resulting in deeper sedation, used larger increments of propofol application and did not assess depth of anaesthesia. This probably resulted in a difficulty to detect smaller differences in propofol requirements between the two groups. Our study design was more sensitive in detecting smaller differences in propofol requirements. We used lidocaine in every cat in order to have a more comparable starting position, whereas in the aforementioned study, only the larynxes of cats getting an ETT were desensitized. This could have led to a lower propofol requirement in the ETT group, thus hiding a real difference between VGEL and ETT.

No significant difference was found between VGEL and LM regarding the total dose of propofol required for placement. There are no comparable studies in cats or other species that would support our findings. But our results are not surprising as both devices are supraglottic airway devices and therefore there is no need to completely abolish airway reflexes as with endotracheal intubation (Cassu et al. 2004).

No significant difference in total propofol requirement for placement of LM and ETT was found. This is in contrast to a study performed in cats where level of anaesthesia required for insertion of the ETT was higher than for the LM (Cassu et al. 2004). A lower dose of induction agent for the insertion of an LM versus an ETT has been shown in other species such as dogs (Wiederstein et al. 2006) and humans (Brain et al. 1985; Blake et al. 1992;

Wilkins et al. 1992; Casati et al. 1999). The median dose of propofol in this study was 3 mg kg^{-1} for LM versus 5 mg kg^{-1} for ETT, which suggests that even though there was no statistically detectable difference, there was a trend towards a lower propofol requirement for the LM group.

The number of attempts for insertion was not significantly different between VGEL, LM and ETT. The placement of VGEL caused difficulties in some cats: one cat showed persistent signs of upper airway obstruction despite testing 2 different sizes. Data of a second cat had to be excluded due to SpO_2 reading below 90%; this low measurement was possibly caused by the epiglotic rest of the VGEL leading to reduced blood flow in the tongue. Using another location for the pulse oxymetry probe could circumvent this problem. Choosing the appropriate size of the VGEL posed a problem in some cats despite a dedicated guideline. In contrast the LM size 1 could be used in all cats of the LM group.

During spontaneous ventilation no leakage was found in any group. This is in agreement with a study in cats that found no clinically significant leakage during spontaneous breathing with VGEL or ETT (van Oostrom et al. 2013).

The leakage was comparable during CMV in group VGEL and LM. In contrast, significantly more animals with ETT showed a leakage of > 20 % of TV during CMV compared to the supraglottic airway devices. This finding is surprising as we expected the ETT to have the least amount of leakage due to its sealing cuff. One study in cats could not show any obvious leakage comparing LM and ETT in cats using peak inspiratory pressure up to 13 cm H_2O (Cassu et al. 2004). In contrast to our study, the endotracheal cuff pressures in that study ranged from to 60 up to 100 mm Hg. Inflation of the low-pressure-high-volume cuff of the ETT up to 20 cm H_2O is known to prevent any mucosal damage of the trachea due to compression and is the reason why we chose a cuff pressure of 20 cm H_2O (Loeser et al. 1978; Seegobin & van Hasselt 1984; Joh et al. 1987). This could have led to the higher incidence of leakage.

In our study, we detected leakage by measuring the difference between the inspiratory and expiratory volumes whereas in other studies this was done by measuring the peak concentration of isoflurane in the vicinity of the mouth or checking for its audibility (Cassu et al. 2004; van Oostrom et al. 2013). From the authors' point of view, those methods are unable to exactly quantify the mL of leakage per breath.

In group LM, two female cats were diagnosed with bloating of the stomach by the surgeon after opening the abdomen. Bloating was not detected in any other female during laparotomy. However, the authors can not exclude bloating in the 15 males during CMV. From human medicine it is known that there is an increased risk for gastro- oesophageal reflux and possible aspiration with the use of a LM because of gastric bloating caused by an insufficient sealing of the glottis, especially during CMV (Valentine et al. 1994). In this study occurrence of gastric reflux during spontaneous and controlled mechanical ventilation was not investigated. Interestingly, one study in cats found a higher incidence of gastric reflux during CMV using ETT compared to LM, without leading to pulmonary aspiration (Cassu et al. 2004). Based on this possible complication the manufacturers of VGEL declare that the tip of the device forms a seal in the oesophageus preventing subsequent aspiration of possible gastric reflux. Further studies are needed verifying and focussing on this issue.

The main limitation of our study is that the positioning of the cat was not changed during the study period. Therefore, no statement on displacement of the devices during repositioning can be made.

Larger prospective clinical trials will be needed to confirm the benefits and/or drawbacks described in this study of the use of VGEL for airway management in cats.

In conclusion, VGEL seems to be a feasible alternative to the classical LM and ETT for securing the airway after induction of anaesthesia and for CMV up to 16 cm H_2O in healthy cats. Insertion of VGEL can be achieved at a more superficial level of anaesthesia compared

with endotracheal intubation and showed significantly less leakage during CMV compared to ETT.

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Table 1 Age, body weight, body condition scores (BCS) and total sedation scores after premedication for groups VGEL, laryngeal mask (LM) or endotracheal tube (ETT). Values are given as median [range].

Parameter	VGEL	LM	ETT
Age (years)	0.7 [0.5-5]	0.7 [0.5-9]	0.5 [0.3-5]
Weight (kg)	3.1 [2.4-5.3]	3.2 [2.5-5.1]	3.1 [2.3-5]
BCS (1-9)	5 [3-7]	5 [3-6]	5 [4-6]
Sedation score (0-15)	8 [0-15]	6 [0-12]	11 [1-15]

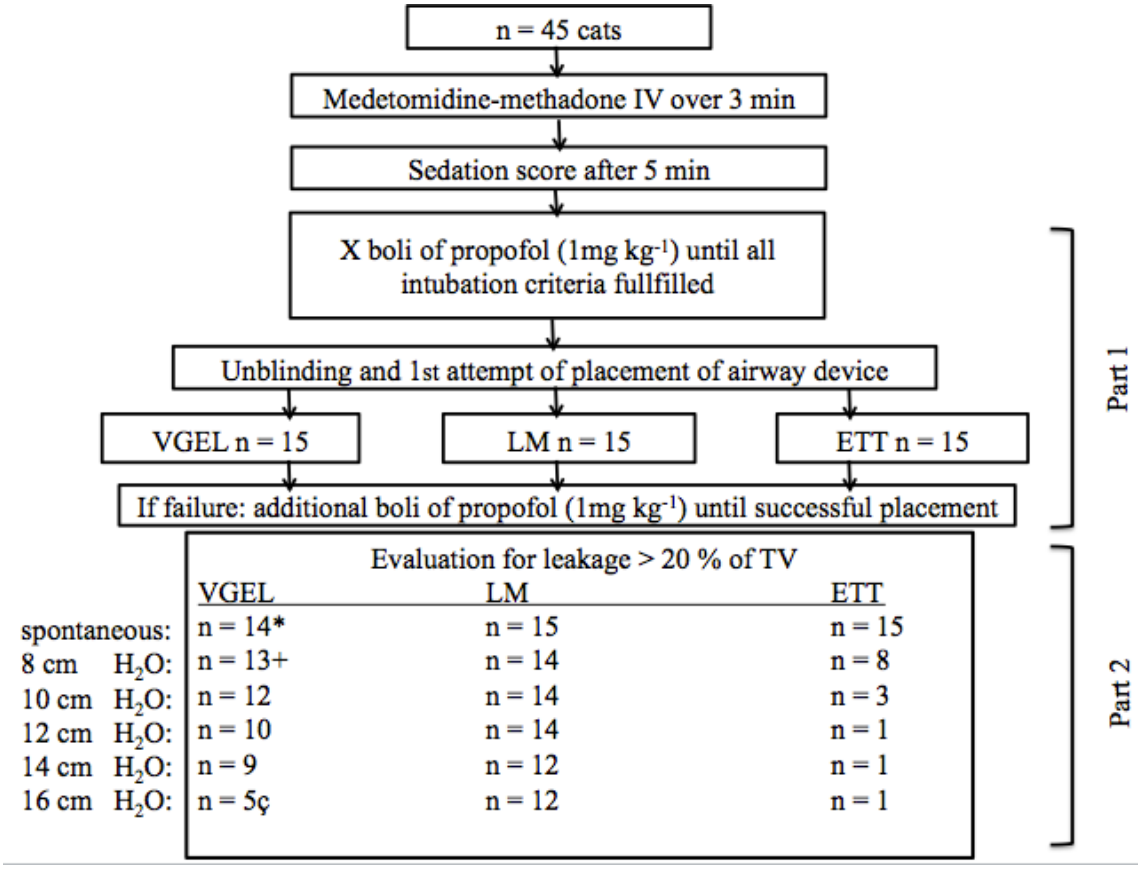

Figure 1 Flow diagram comparing the total dose of propofol required for the placement of a VGEL, laryngeal mask (LM) or endotracheal tube (ETT) and the occurrence of a leakage > 20 % of tidal volume (TV) with spontaneous and controlled mechanical ventilation (CMV) at 8, 10, 12, 14 and 16 cm H_2O. * One cat in the VGEL group could not be included for the 2nd part of the study due to airway problems. + One cat was excluded during CMV because of decreased pulsoxymetry reading. ç One cat had to be excluded at 16 cm H_2O due to problems with ventilation. IV = intravenuous

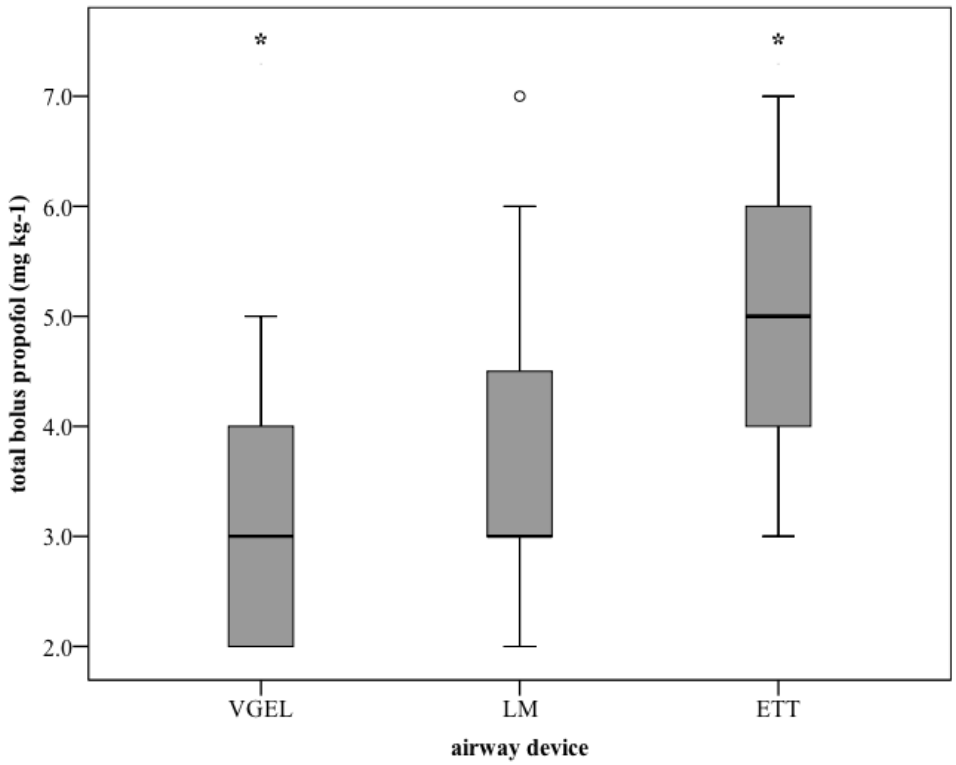

Figure 2 Median and interquartile range of total dose of propfol required for successful insertion of a VGEL, laryngeal mask (LM) or endotracheal tube (ETT). One cat in the LM needed 7 mg kg^{-1} of propofol (white circle).* Denotes significant difference between VGEL and ETT.

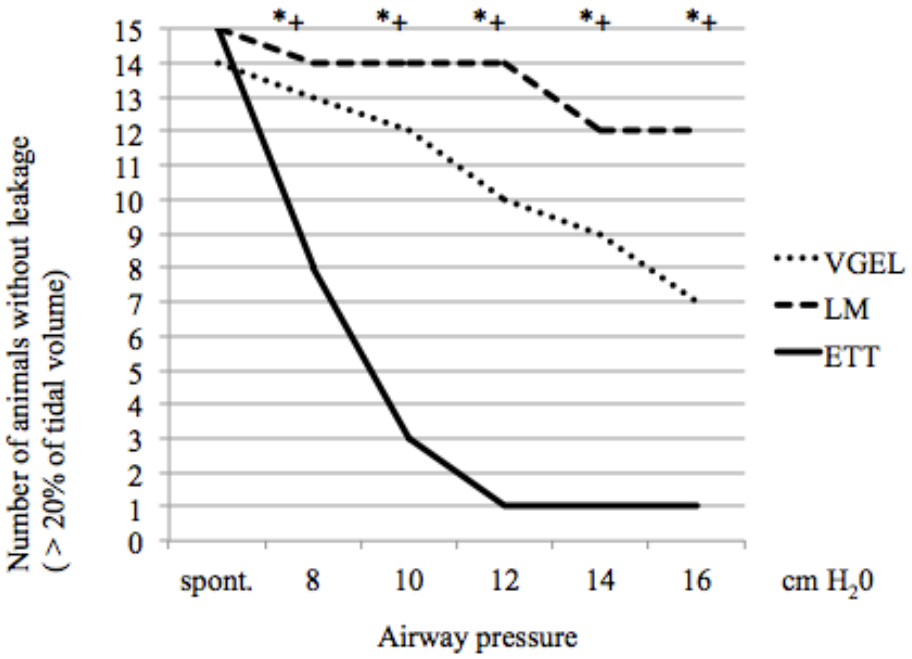

Figure 3 Kaplan-Meier graph: number of animals without leakage (> 20 % of tidal volume) during spontaneous and controlled mechanical ventilation at pressure settings of 8, 10 , 12, 14 and 16 cm H_2O with VGEL, laryngeal mask **(**LM**)** and endotracheal tube **(**ETT**)**. + Significant differences between VGEL and ETT.

* Significant differences between LM and ETT. There was no significant difference between the VGEL and LM group at any of the pressure settings. 3 cats in VGEL group were excluded due to technical problems other than leakage (Figure 1).

Appendix 1 Criteria for assessment of insertion of a VGEL, LM or ETT (modified from Gurney et al. 2009).

Assessed Criteria	**Result required for proceeding to next criteria**
1st Palpebral reflex	Weak
2nd Jaw tone	No resistance
3rd Protraction of tongue	No resistance/swallowing
4th Laryngoscope on tongue	No swallowing/ gagging/ retching
5th Lidocaine on larynx	No swallowing/ gagging/ retching
→ Allocation to VGEL/LM/ETT and first attempt of insertion/intubation in sedation	

Lebenslauf

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